DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

3/10/98

D1362B

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-98-22

January 21, 1998

FACILITY ID# 173468

Jaime Pozo, Administrator
Radiological Services of Miami
8000 W. Flagler St.
Suite 101
Miami, Florida 33144

Dear Mr. Pozo:

Your facility was inspected on January 7, 1998 by a representative of the U. S. Food and Drug Administration. This inspection revealed that your facility fails to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

- The radiologic technologist, [redacted] does not meet the requirements of being licensed by a state or board certified by any of the approved boards.

The specific deficiency noted above appeared under the Level 1 heading on your MQSA Facility Inspection Report, which was issued at the close of the inspection. In addition, the following Level 2 noncompliances were listed on the inspection report provided to you at the close of the inspection. These level 2 noncompliances include:

- Forty percent of the data points for either medium density, density difference, or base plus fog were missing for the month of August 1997 for the Kodak X-Omat M35 or M35A-M developers.

- The radiologic technologist, [redacted] does not have specific training in mammography.

These specific deficiencies appear on the List of Observations which was issued to your facility on January 16, 1998. These deficiencies may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the cause of these deficiencies that the inspection identifies and to promptly initiate permanent corrective actions.

If you fail to properly address these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may: impose civil money penalties on a facility of up to $10,000 for each failure to substantially comply with, or each day of failure to comply with the Standards, suspend or revoke a facility's FDA certificate for failure to comply with the Standards, seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Within 15 working days after receiving this letter, you should notify FDA in writing of each step your facility is taking to prevent the recurrence of similar violations.

If your facility is unable to complete the corrective actions within 15 working days, you should state the reason for the delay and the time within which the correction will be completed.

Your reply should be directed to Timothy Couzins, Compliance Officer, U.S. Food and Drug Administration, 7200 Lake Ellenor Dr Suite 120, Orlando Fl 32809, telephone (407)648-6823, extension 264. Any questions in regard to this letter or how to ensure you are meeting MQSA standards, please call Carlos I. Medina, C.S.O., at 305-526-2800, extension 924.

Sincerely,

Edward R. Atkins

Douglas D. Tolen
Director, Florida District